UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

SARA ARTERBURN,	§	
Plaintiff,	§	
	§	
vs.	§	**Civil Action No. _____**
	§	
BAYER HEALTHCARE	§	
PHARMACEUTICALS, INC.	§	
Defendant.	§	

COMPLAINT WITH JURY DEMAND

Plaintiff Sara Arterburn ("Plaintiff"), by and through the undersigned attorneys, hereby brings this cause of action for personal injuries suffered as a proximate result of Plaintiff Sara Arterburn being prescribed and using the defective and unreasonably dangerous product Mirena® (levonorgestrel-releasing intrauterine device). At all times relevant hereto, Mirena® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by the named Defendant.

PARTIES

1. At all relevant times hereto, Plaintiff Sara Arterburn was a resident and citizen of Tarrant County, Texas.

2. Defendant Bayer Healthcare Pharmaceuticals Inc. (hereinafter "Bayer" or "Defendant") is and at times relevant was, a corporation organized and existing under the laws of the State of Delaware, with its principal place of business and headquarters in the State of New Jersey. Defendant Bayer may be served by delivering the petition to its registered agent for service, CSC – Lawyers Incorporating Service Company, 211 E. 7th Street, Suite 620, Austin, Texas 78701-3218.

3. Defendant Bayer Healthcare Pharmaceuticals Inc. is the holder of the approved New Drug Application ("NDA") for contraceptive device Mirena®.

4. Bayer Healthcare Pharmaceuticals Inc. is in the business of designing, manufacturing, and marketing prescription drugs and women's healthcare products, including the intrauterine contraceptive device, Mirena®.

5. Bayer Healthcare Pharmaceuticals Inc. does business in Texas through the sale of Mirena® and other prescription drugs in the state.

6. At all times alleged herein, Defendant includes, and included, any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

7. At all times relevant, Defendant was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device, Mirena®.

8. At all times relevant herein, the Defendant was in the business of designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing prescription drugs and women's healthcare products, including the intrauterine contraceptive device, Mirena®.

JURISDICTION AND VENUE

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendant is incorporated and has their principal place of business a state other than

the state in which the named Plaintiff resides.

10. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred, in part, in the Northern District of Texas, Fort Worth Division.

FACTS

12. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

13. Mirena® is an intrauterine device that is inserted by a healthcare provider during an office visit. Mirena® is a T-shaped polyethylene frame with a steroid reservoir that releases levonorgestrel, a prescription medication used as a contraceptive.

14. The federal Food and Drug Administration (FDA) approved Defendant's New Drug Application for Mirena® in December 2000. Today, more than 2 million women in the United States use Mirena®. It has been used by more than 15 million women worldwide.

15. The device releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control. Defendant admits "it is not known exactly how Mirena® works," but provides that Mirena® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

16. The Mirena® intrauterine device ("IUD") is designed to be placed within seven (7) days of the first day of menstruation and is approved to remain in the uterus for up to five (5) years. If continued use is desired after five years, the old device must be discarded and a new one inserted.

17. The package labeling recommends that Mirena® be used in women who have had at least one child.

18. Mirena®'s label does not warn about spontaneous migration of the IUD, but only states that migration may occur if the uterus is perforated during insertion.

19. Mirena®'s label also describes perforation as an "uncommon" event, despite the numerous women who have suffered migration and perforation post-insertion, clearly demonstrating this assertion to be false.

20. Defendant has a history of overstating the efficacy of Mirena® while understating the potential safety concerns.

21. In or around December 2009, Defendant was contacted by the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications (DDMAC) regarding a consumer-directed program entitled "Mirena® Simple Style Statements Program" a live presentation designed for "busy moms." The Simple Style program was presented in a consumer's home or other private setting by a representative from "Mom Central," a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendant.

22. This Simple Style program represented that Mirena® use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined these claims were unsubstantiated and, in fact, pointed out that Mirena®'s package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

23. The Simple Style program script also intimated that Mirena® use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that Mirena® can cause a number of side effects, including weight gain, acne, and breast pain or

tenderness.

24. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage if a woman becomes pregnant on Mirena®.

25. Finally, Defendant falsely claimed that Defendant's product required no compliance with a monthly routine.

26. Plaintiff Sara Arterburn is currently 31 years-old.

27. Plaintiff had the Mirena® IUD inserted on or about August 10 2011, by Dr. Stephanie Pickel in Mansfield, Texas. While she experienced some mild discomfort, the insertion was completed.

28. Plaintiff underwent a pelvic ultrasound approximately 3 weeks later, which confirmed IUD placement.

29. Because of continued pain, Plaintiff had a follow-up visit on or about September 13, 2011. At which time, the IUD strings could not be seen, but there were no other indications of any problems.

30. During Plaintiff's annual exam on February 21, 2012, Plaintiff was informed that the strings of the Mirena® were in place, indicating to her that the IUD was properly positioned.

31. On March 27, 2012, Plaintiff returned to Dr. Pickel's office after having several positive at home pregnancy tests. Pregnancy was confirmed. Upon initial examination, Dr. Pickel was unable to see the strings of the Mirena®. The subsequent sonogram showed the IUD in the lower uterine segment. Dr. Pickel attempted to remove the Mirena® under the guidance of the sonogram, but was unsuccessful. At that point, it was determined that a more aggressive attempt at removal could be dangerous for the fetus and efforts to remove the device were

stopped.

32. Plaintiff underwent an ultrasound on April 11, 2012, at approximately 8 weeks 6 days pregnant. The IUD was no longer visible on the sonogram. It was expected that the Mirena® would be expelled during delivery.

33. On or about October 27, 2012, Plaintiff gave birth. The Mirena® was not found at delivery. A KUB x-ray following the delivery revealed that the Mirena® had migrated and was in the upper left quadrant of Plaintiff's abdomen.

34. An abdominal x-ray performed on December 3, 2012 showed the IUD to be in the pelvis and suggested an extrauterine location based on the orientation and positioning of the device.

35. Approximately six weeks after delivery, on December 11, 2012, Plaintiff underwent Laparoscopic bilateral tubal ligation with IUD removal. During the surgery, the Mirena® IUD was located on top of Plaintiff's omentum with partial embedment. Dr. Stephanie Pickel used a Maryland instrument to move the IUD and the omentum to the lower abdomen where she made a 5 mm incision to insert a 5 mm trocar and was able to use a second grasper to bluntly dissemble the IUD.

CAUSES OF ACTION
PRODUCT DEFECT IN DESIGN OR FORMULATION

36. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

37. At all times herein mentioned, Defendant manufactured, designed, formulated, produced, created, made, constructed and/or assembled Mirena®, used by Plaintiff.

38. Defendant's Mirena® was defective in that at the time Mirena® left the control of

Defendant, the foreseeable risks associated with its design or formulation exceeded the benefits associated with that design or formulation.

39. Mirena® was in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous to its users and, in particular, Plaintiff.

40. At all times herein mentioned, Mirena® was in a defective condition and unsafe, and Defendant knew, had reason to know, or should have known that said Mirena® was defective and unsafe, especially when used as instructed and in the form and manner as provided by Defendant.

41. The nature and magnitude of the risk of harm associated with the design and formulation of Mirena®, including uterine migration and perforation, is high in light of the intended and reasonably foreseeable use of Mirena® as a reversible form of contraceptive.

42. It is highly unlikely that Mirena® users would be aware of the risks associated with Mirena® through either warnings, general knowledge or otherwise. Plaintiff was not aware of said risks.

43. The likelihood was high that the design or formulation would cause the harm of uterine migration and perforation, in light of the intended and reasonably foreseeable use of Mirena® as a reversible form of contraceptive.

44. The design or formulation did not conform to any applicable public or private product standard that was in effect when Mirena® left the control of its manufacturer, the Defendant.

45. The design or formulation of Mirena® is more dangerous than a reasonably prudent consumer would expect when used in the intended or reasonable foreseeable manner as a reversible form of contraceptive. It was more dangerous than Plaintiff expected.

46. The intended or actual utility of Mirena® is not of such benefit to justify the risk of uterine migration, perforation and even infertility.

47. There was both technical and economic feasibility, at the time Mirena® left Defendant's control, of using an alternative design or formulation that would not cause uterine migration or perforation.

48. The defective design or formulation of Mirena® was not caused by an inherent characteristic of the Mirena® which is a generic aspect of all contraceptive medications that cannot be eliminated without substantially compromising Mirena®'s usefulness or desirability and which is recognized by the ordinary person. This is demonstrated by numerous safer alternative therapies that are available on the market to prevent contraception, without the harmful side effects that can result from Mirena® use.

49. Defendant manufactured, marketed, promoted and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by the Plaintiff Sara Arterburn.

50. As a direct and proximate cause of Plaintiff Sara Arterburn's use of Mirena®, she had to undergo surgical removal of the IUD, developed severe pain and bleeding caused by the perforation, and had to have a hysterectomy as a result.

51. Defendant placed Mirena® into the stream of commerce with wanton and reckless disregard for the public safety.

52. Defendant knew and, in fact, advertised and promoted the use of Mirena® despite their failure to test or otherwise determine the safety and efficacy of such use. As a direct and proximate result of the Defendant's widespread promotional activity, physicians began commonly prescribing this product as safe and effective.

53. A practical and technically feasible alternative design or formulation was available that would have prevented the harm for which Plaintiff suffered.

54. Despite the fact that evidence existed that the use of Mirena® was dangerous and likely to place users at serious risk to their health, Defendant failed to disclose and warn of the health hazards and risks associated with the Mirena® and in fact acted to deceive the medical community and public at large, including all potential users of Mirena® by promoting it as safe and effective.

55. Defendant knew or should have known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive despite its lack of efficacy and potential for serious permanent side effects.

56. There are contraceptives on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk.

57. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Sara Arterburn suffered profound injuries, required medical treatment, and incurred medical and hospital expenses.

58. By reason of the foregoing, the Defendant is liable to the Plaintiff for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective in design and formulation, and in violation of Texas Civil Practice & Remedies Code §82.005.

PRODUCT DEFECT DUE TO INADEQUATE WARNING AND/OR INSTRUCTION

59. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

60. Defendant had a duty to warn Plaintiff of the risks associated with Mirena®, namely, the risk of spontaneous migration and uterine perforation.

61. Defendant knew, or in the exercise of reasonable care, should have known about the risk that Mirena® causes spontaneous migration and uterine perforation.

62. Defendant failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of spontaneous migration and uterine perforation, in light of the likelihood that their product would cause spontaneous migration and uterine perforation, of which Plaintiff suffered.

63. Defendant's Mirena® is defective due to inadequate post-marketing warning or instruction.

64. Defendant failed to provide post-marketing warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of spontaneous migration and uterine perforation, in light of the likelihood that the product causes spontaneous migration and uterine perforation, for which Plaintiff suffered.

65. Defendant's Mirena® does not contain a warning or instruction regarding spontaneous migration and uterine perforation for normal healthy individuals.

66. The risk of spontaneous migration and uterine perforation is not an open and obvious risk or a risk that is a matter of common knowledge in regards to Mirena®.

67. Although Defendant knew, or was reckless in not knowing, of the defective nature of Mirena®, they continued to design, manufacture, market, and sell Mirena® without providing adequate warnings and instructions concerning the use of Mirena® so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Mirena®.

68. By reason of the foregoing, the Defendant is liable to the Plaintiff, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective due to inadequate warning or instruction.

FRAUD BY CONCEALMENT

69. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth and further alleges as follows:

70. Defendant had a duty and obligation to disclose to Plaintiff Sara Arterburn that the aforesaid product was dangerous and likely to cause serious health consequences to users when used as prescribed.

71. Defendant intentionally, willfully, and maliciously concealed and/or suppressed the facts set forth above from Plaintiff Sara Arterburn with the intent to defraud her as herein alleged.

72. Neither Plaintiff Sara Arterburn nor her physicians were aware of the facts set forth above, and had they been aware of said facts would not have prescribed this product.

73. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiff Sara Arterburn has proximately sustained damage, as set forth herein.

74. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Sara Arterburn suffered profound injuries that required medical treatment and incurred medical and hospital expenses.

FRAUDULENT AND/OR NEGLIGENT MISREPRESENTATION

75. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth and further alleges as follows:

76. Defendant, having undertaken the manufacturing, marketing, prescription,

dispensing, distribution and promotion of Mirena® described herein, owed a duty to provide accurate and complete information regarding Mirena®.

77. Defendant fraudulently and/or negligently misrepresented material facts and information regarding Mirena® including, but not limited to, its propensity to cause serious physical harm.

78. At the time of Defendant's fraudulent and/or negligently misrepresentations and omissions, Plaintiff Sara Arterburn was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

79. Defendant knew this information to be false, incomplete and misleading information.

80. Defendant intended to deceive and mislead Plaintiff Sara Arterburn so that she might rely on these fraudulent misrepresentations.

81. Plaintiff Sara Arterburn had a right to rely on and did reasonably rely upon Defendant's deceptive, inaccurate and fraudulent misrepresentations.

82. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Sara Arterburn suffered profound injuries that required medical treatment and incurred medical and hospital expenses.

STRICT LIABILITY

83. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

84. Defendant is a manufacturer and/or supplier of Mirena® and is strictly liable to Plaintiff for designing, creating, manufacturing, distributing, selling and placing Mirena® into the stream of commerce.

85. The Mirena® manufactured and/or supplied by Defendant was defective in design or formulation in that, when it left the hands of the manufacturer and/or supplier, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than other contraceptives.

86. Mirena® was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

87. Mirena® was also defective due to inadequate warnings or instructions because the manufacturer knew or should have known that Mirena® created, among other things, a risk of perforation and migration and associated infections or conditions and the Defendant failed to adequately warn of these risks.

88. Mirena® was defective due to inadequate pre-marketing testing.

89. Defendant failed to provide adequate initial warnings and post-marketing warnings or instructions after the manufacturer and/or supplier knew or should have known of the extreme risks associate with Mirena® and continues to promote Mirena® in the absence of those adequate warnings.

90. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendant, Plaintiff Sara Arterburn suffered profound injuries, required medical treatment, and incurred medical and hospital expenses.

BREACH OF IMPLIED WARRANTIES

91. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth and further alleges as follows:

92. Defendant supplied the product in question in a condition unfit for the ordinary

purpose for which these products are use because the product in question lacked essential properties and mitigating safety measures necessary to make it adequate.

93. The unfit condition of the product in question proximately caused the incident and damages to the Plaintiff.

PRODUCT DEFECT IN FAILURE TO CONFORM TO REPRESENTATIONS

94. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

95. Defendant's product was defective in that, when it left the control of Defendant, the product did not conform to representations made by Defendant.

96. Said representations are false, misleading, and inaccurate.

97. Defendant describes and represents that their product has characteristics that simply do not conform to reality. Rather than acknowledging that Defendant's product causes spontaneous migration and uterine perforation, Defendant describes Mirena® as being safe.

98. These representations are in stark contrast to the spontaneous migration and uterine perforation that Mirena® does actually cause.

99. Plaintiff believes and asserts that Defendant acted negligently and recklessly in making their representations.

100. By reason of the foregoing, the Defendant is liable to the Plaintiff for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective in that it did not conform at the time it left the control of Defendant, to the representations made by Defendant.

NEGLIGENCE

101. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth, and further alleges as follows:

102. Upon information and belief, Defendant failed to use reasonable care in designing Mirena® in that they: (a) failed to properly and thoroughly test Mirena® before releasing the drug to market; (b) failed to properly and thoroughly analyze the data resulting from the pre-marketing tests of Mirena®; (c) failed to conduct sufficient post-market testing and surveillance of Mirena®; designed, manufactured, marketed, advertised, distributed, and sold Mirena® to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Mirena® and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug; (d) failed to exercise due care when advertising and promoting Mirena®; and (e) negligently continued to manufacture, market, advertise, and distribute Mirena® after Defendant knew or should have known of its adverse effects.

103. A reasonable manufacturer would or should have known that its risks created by Mirena® are unreasonably greater than that of other contraceptives and that Mirena® has no clinical benefit over such other contraceptives that compensates in whole or part for the increased risk.

104. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Sara Arterburn suffered profound injuries, required medical treatment, and incurred medical and hospital expenses.

105. Plaintiff's injury was the result of misconduct of Defendant that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question.

106. Defendant fraudulently and in violation of applicable regulations of the FDA

withheld from the FDA, information known to be material and relevant to the harm that the Plaintiff suffered, or misrepresented to the FDA information of that type.

107. By reason of the foregoing, the Defendant is liable to the Plaintiff for punitive damages, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective under Chapter 82 of the Texas Civil Practice & Remedies Code.

PRAYER FOR RELIEF

108. Plaintiff demands judgment against Defendant for compensatory, statutory and punitive damages, along with lost wages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

JURY DEMAND

109. Plaintiff requests a trial by jury.

Respectfully submitted,

GUAJARDO & MARKS, LLP

/s/ J. Gregory Marks

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